The Division of AIDS Cross Training resources for site staff will be included in the protocol Manual of Operation.

The collection of gender identity data allows for a more accurate assessment of HIV infection at birth.

The Brazilian National Commission on Research Ethics (CONEP) did not approve the proposal to IMPAACT Leadership to use the two-step method. However, our institution has a policy against discrimination on the basis of sexual orientation.

Data on sex assigned at birth will be obtained from the medical record.

Youth under the age of 12 will not be asked about their gender identity.

A pilot study was conducted in 2017 to assess the feasibility of using an interview case step method for assessing gender identity in youth (12 years and older).

Overall the questionnaire was well understood and easily completed by most of the participants.

Finding from Pilot

Overall the questionnaire was well-understood and easily completed by most of the 32 respondents.

Understanding cultural differences and risks is important.

- The Broadband National Commission on Research Ethics (CONEP) did not approve participation in the pilot due to "risk of discrimination, stigma, violence and other harmful consequences".

- Vast majority of sites have or are aware of resources that would be available for participants (94% of sites).

- Resources included psychiatrists, psychologists, other mental health providers, pediatrics; nurse specialists, among others at the institution or in the community.

- All sites responding to the survey were a wide range of institutions.

- 2 of the 3 sites in Asia reported having resources.

- 4/13 sites (31%) indicated that discrimination may result from disclosure to family/home.

- 13% of the sites (6/48) indicated that discrimination may result from disclosure to caregivers.

- Most protocols included additional comments, roughly half of which were supportive of asking about gender identity.

- Concerns included the added burden on site personnel; costs associated with referrals; community expectations for more holistic care; agreements of care; fear of stigma and discrimination may affect the quality of data collected since some of the information may be concealed by participants; safety. However, our institution has a policy against discrimination on the basis of sexual orientation.

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- 13/42 sites (31%) said there would be a cost involved in accessing resources (two sites did not respond).

- The issues identified related to:
  - Legal concerns: limitations of law and government support
  - Interpretation that study is promoting LGBT practices
  - Need to use legal name on informed consent documentation
  - Need for IRB approval

- One US site identified a unique policy that prohibits asking about sex assigned at birth, gender identity or transition-related interventions unless it is necessary to protect the participant.

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